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IBSA Institut Biochimique SA,
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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IBSA INSTITUT BIOCHIMIQUE SA, IBSA
PHARMA INC., and ALTERGON SA,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.,

Defendant.

C.A. No. 23-54 (SRC)(JBC)

(Filed Electronically)

STIPULATION AND

ORDER

WHEREAS, on January 5, 2023, Plaintiffs IBSA Institut Biochimique SA, IBSA Pharma Inc., and Altergon SA (collectively, “Plaintiffs”) filed a Complaint for Patent Infringement against Defendant Accord Healthcare, Inc. (“Accord”), alleging that Accord’s submission of Abbreviated New Drug Application (“ANDA”) No. 218008, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Tirosint®-SOL (levothyroxine sodium oral solution) (“Accord’s ANDA Product”), infringes U.S. Patent Nos. 10,537,538 and 11,096,913 (the “’538 patent” and “’913 patent,” respectively);

WHEREAS, on November 16, 2023, the U.S. Food and Drug Administration (“FDA”) approved revised labeling for Tirosint®-SOL;

WHEREAS, on December 14, 2023, U.S. Patent No. 11,241,382 (the “’382 patent”) was listed in the FDA’s publication entitled “Approved Drug Products with Therapeutics Equivalence Evaluations” (the “Orange Book”) for Tirosint®-SOL in view of the FDA’s November 16, 2023 approval of revised labeling;

WHEREAS, on February 20, 2024, Accord sent Plaintiffs’ counsel its Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’382 patent;

WHEREAS, the statutory stay of FDA approval of Accord’s ANDA No. 218008 (“30-month stay”) currently expires on May 28, 2025; and

WHEREAS, the current case schedule (ECF No. 49) provides for approximately seven (7) months between the submission of a proposed Final Pretrial Order and the expiration of the 30-month stay.

NOW THEREFORE, the parties, through their respective undersigned counsel, and subject to the approval of the Court, stipulate that:

1. The 30-month stay as to Accord’s ANDA No. 218008 is extended from May 28, 2025 until November 28, 2025. Accord agrees to notify the FDA of this Order as soon as practicable and in any event no later than 30 days after being entered by the Court.
2. Accord agrees to refrain from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord’s ANDA Product within the United States until after November 28, 2025, unless before that date, the Court finds all asserted claims of the ’538 patent, ’913 patent, and ’382 patent not infringed or invalid. Plaintiffs and Accord further agree that nothing herein shall prevent or preclude Accord from engaging in the

commercial manufacture, use, offer for sale, sale, and/or importation of Accord's ANDA Product within the United States after November 28, 2025.

3. Plaintiffs and Accord further agree that nothing herein shall prevent or preclude Plaintiffs from filing a motion for an injunction (or seeking any other relief from the Court, as appropriate) to prevent Accord from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's ANDA Product within the United States after November 28, 2025.
4. The case schedule shall be amended as follows:

Event	Current Date (ECF No. 49)	Amended Date
Amend Complaint to allege infringement of '382 patent	N/A	April 19, 2024
Disclosure of asserted claims for '382 patent	N/A	April 26, 2024
Defendant serves non-infringement and invalidity contentions for '382 patent	N/A	May 20, 2024
Plaintiffs serves infringement and validity contentions for '382 patent	N/A	July 3, 2024
Parties exchange proposed claim terms for construction for '382 patent	N/A	July 10, 2024
Parties exchange preliminary claim constructions and evidence for '382 patent	N/A	July 24, 2024
Parties exchange responding claim construction and evidence for '382 patent	N/A	August 7, 2024
Joint claim construction statement for '382 patent	N/A	August 23, 2024
Substantial completion of document production for '382 patent	N/A	September 13, 2024
Completion of claim construction fact discovery for '382 patent	N/A	September 23, 2024
Opening <i>Markman</i> briefs for '382 patent	N/A	October 7, 2024

<i>Markman</i> discovery closes for '382 patent	N/A	October 28, 2024
Responsive <i>Markman</i> briefs for '382 patent	N/A	November 6, 2024
<i>Markman</i> hearing for '382 patent	N/A	<i>To be scheduled by this Court</i>
Deadline to move to amend or add parties	April 22, 2024	November 1, 2024
Close of fact discovery (all patents)	April 29, 2024	November 8, 2024
Opening expert reports on issues for which the party bears the burden of proof (all patents)	May 22, 2024	December 5, 2024
Rebuttal expert reports (all patents)	July 12, 2024	January 15, 2025
Reply expert reports (all patents)	August 7, 2024	February 14, 2025
Close of expert discovery (all patents)	September 6, 2024	March 13, 2025
Submission of proposed Final Pretrial Order	October 14, 2024	April 16, 2025
Final Pretrial Conference	<i>To be scheduled by this Court</i>	<i>To be scheduled by this Court</i>
Trial	<i>To be scheduled by this Court</i>	<i>To be scheduled by this Court</i>
Expiration of FDA stay of approval of ANDA No. 218008	May 28, 2025	November 28, 2025

SO ORDERED on this 7th day of May, 2024.

s/ Stanley R. Chesler

Hon. Stanley R. Chesler, U.S.D.J.

Dated: April 18, 2024

SO STIPULATED:

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